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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,495	11/13/2000	Bruce Joseph Roser	P65952US0	9084

136 7590 06/18/2002

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EXAMINER

HENRY, MICHAEL C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 06/18/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/623,495

Applicant(s)

ROSER ET AL.

Examiner

Michael C. Henry

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15 are pending in application

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 3 and 7, the phrase "at least 0.25:1 preferably 0.5:1" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1623

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Foster et al. (US 6,258,341 B1).

In claim 1, applicants' claim a method of drying, without damage, a compound which is subject to deactivation on drying, or a mixture of such compounds, comprising subjecting an aqueous system containing the compound or mixture to drying in the presence of one or more monosaccharide sugar alcohols and at least one additive which is a glass-former or a glass formation-facilitator, whereby the compound solidifies from solution as an amorphous glass rather than forming crystals. Foster et al. disclose a method of drying, without damage, a compound (Human zinc insulin) which is subject to deactivation on drying, or a mixture of such compound, comprising subjecting an aqueous system containing the compound or mixture to drying in the presence of one a sugar alcohol (mannitol) and at least one additive (sodium citrate) which is a glass-former or a glass formation-facilitator, whereby the compound solidifies from solution as an amorphous glass rather than forming crystals (example 3, col. 23; see also, table 1, col. 14, lines 49-65). Claims 2-9 are also rejected because, the limitations and/or dependability encompassed by these claims are also anticipated by Foster et al. (example 3, col. 23).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foster et al. (US Patent No. 6,258,341 B1).

In claim 1, applicants' claim 'a method of drying, without damage, a compound which is subject to deactivation on drying, or a mixture of such compounds, comprising subjecting an aqueous system containing the compound or mixture to drying in the presence of one or more monosaccharide sugar alcohols and at least one additive which is a glass-former or a glass formation-facilitator, whereby the compound solidifies from solution as an amorphous glass rather than forming crystals.' In claims 11-13 applicants claim a method or product according to claim 1 pertaining to specific additives or to monosaccharide alcohols.

Foster et al. disclose a product and method of drying, without damage, a compound (Human zinc insulin) which is subject to deactivation on drying, or a mixture of such compound, comprising subjecting an aqueous system containing the compound or mixture to drying in the presence of one a sugar alcohol (mannitol) and at least one additive (sodium citrate) which is a glass-former or a glass formation-facilitator, whereby the compound solidifies from solution as an amorphous glass rather than forming crystals (example 3, col. 23; see also, table 1, col. 14, lines 49-65). In addition, Foster et al. disclose a method and product of elcatonin powder prepared from elcatonin and glass formers and additives (example 18, col. 43).

The difference between applicants claimed method or product and the method or product that is exemplified by Foster et al. is that, Foster et al. do not disclose the identical glass formers or additives like those claimed by the applicants'. However, Foster et al. suggest that additives used by the applicants including, peptides, proteins, and salts like calcium lactate, sodium tetraborate can be used (col. 12, lines 25-37), (col. 13, lines 13-20), (col. 12, line 65 to col. 13,

Art Unit: 1623

line 12). Foster et al. also suggest that monosaccharide sugar alcohols other than mannitol (like xylitol and sorbitol) can be used (col. 11, lines 24-36).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to use the method of drying of Foster et al. to prepare amorphous glass of products of compounds using different monosaccharide sugar alcohols and additives.

One having ordinary skill in the art would have been motivated, in view of Foster et al., to prepare amorphous glass of products of compounds using different monosaccharide sugar alcohols and additives, depending on cost, availability and/or convenience of use. The preparations of different amorphous glass compositions are well known in the art.

In claim 15, applicants claim a method or product according to claim 1 wherein the amorphous glass is formed from a formulation having essentially a composition selected from: (12). Mannitol 50%, and dextran 50%.

Foster et al. disclose a method and product of claim 1 consisting of mannitol and other additives (example 3, col. 23).

The difference between applicants claimed method or product and the method or product that is exemplified by Foster et al. is that, Foster et al. do not disclose the use of dextran in combination with mannitol. However, Foster et al. suggest that dextran is a glass former (see table 1, col. 14, lines 49-65). In addition, Foster et al. use more than one additive in his method.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to use the method of drying of Foster et al. to prepare amorphous glass of products of compounds using different monosaccharide sugar alcohols and/or additives in different percent combinations.

Art Unit: 1623

One having ordinary skill in the art would have been motivated, in view of Foster et al., to prepare amorphous glass of products of compounds using different monosaccharide sugar alcohols and/or additives in different percent combinations, depending on cost, availability and/or convenience of use. The preparations of different amorphous glass compositions are well known in the art.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 703 308-7307. The examiner can normally be reached on 8:00 am to 4:30pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 703 308-4532. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

June 13, 2002


SAMUEL BARTS
PRIMARY EXAMINER
GROUP 1200